UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

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BRENDA LEUZZI and GEORGE LEUZZI,

Plaintiffs,

-against-

ETHICON ENDO SURGERY, INC., d/b/a ETHICON WOMEN'S HEALTH AND UROLOGY and ABC CORPORATIONS 1-10 and JOHN DOES 1-10 and JANE DOES 1-10,

Defendants.

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DOCKET NO:

VERIFIED COMPLAINT

Plaintiffs, BRENDA LEUZZI and GEORGE LEUZZI, by their attorneys, ALONSO KRANGLE LLP, complaining of the defendants, respectfully alleges, upon information and belief, as follows

I. INTRODUCTION

1. This action is a products liability action against Ethicon Endo Surgery, Inc., d/b/a Ethicon Women's Health and Urology ("ETHICON") as well as ABC Corporations, 1-10, John Does, 1-10, and/or Jane Does, 1-10, resulting from the use of said defendants' morcellator surgical products.

2. Plaintiff BRENDA LEUZZI, had a surgical procedure performed on her known as a Robot-assisted hysterectomy with uterine morcellation in September 2012 at The Strong Memorial Hospital of the University of Rochester Medical Center.

II. JURISDICTION AND VENUE

3. This Court has original jurisdiction pursuant to 28 U.S.C. §1332, as the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different states as plaintiffs BRENDA LEUZZI and GEORGE

LEUZZI, are residents of the state of New York and defendants are residents of the State of New Jersey.

4. Venue in the Western District of New York is proper under 28 U.S.C. §1391(b)(2) as a substantial part of the events or omissions giving rise to the claim occurred in this District.

III. PARTIES

5. Plaintiffs BRENDA LEUZZI and GEORGE LEUZZI are adult individuals residing in Fairport, New York.

6. Defendant ETHICON, is a corporation, or other entity, organized and/or existing under the laws of the New Jersey, and who at all times material and relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or and/or designing and/or distributing minimally invasive gynecological surgical products, with a principal place of business at Route 22 West, Somerville, New Jersey.

7. Defendants ABC Corporations, 1-10, are fictitious names, corporations, or other similar entities who were engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, specifically, the product/s used upon Plaintiff.

8. John Does, 1-10, who were engaged in the business manufacturing and/or selling and/or supplying and/or marketing and/or distributing minimally invasive gynecological surgical products, specifically, the product/s used upon Plaintiff.

9. Jane Does, 1-10, who were engaged in the business manufacturing and/or selling and/or supplying and/or marketing and/or distributing minimally invasive gynecological surgical products, specifically, the product/s used upon Plaintiff.

10. In September 2012 plaintiff BRENDA LEUZZI underwent a surgical procedure known as a Robot-assisted hysterectomy with uterine morcellation at the Strong Memorial Hospital of the University of Rochester Medical Center.

11. Prior to the Plaintiff's surgery in September 2012 there was no evidence of disseminated and/or metastatic cancer/disease.

12. Following this procedure, in September 2012 Plaintiff was informed that she had cancer.

13. Plaintiff has been undergoing aggressive treatment and therapy since learning of her cancer diagnosis.

14. It is alleged that each and every defendant herein failed to warn about the possibility of dissemination of an occult uterine leiomyosarcoma throughout the peritoneal cavity.

15. Defendants were each aware of the risks, complications, and/or adverse events associated with their products used for uterine morcellation.

COUNT I – NEGLIGENCE
ON BEHALF OF PLAINTIFF BRENDA LEUZZI

16. The paragraphs above are incorporated by reference hereto as if set forth at length.

17. Defendants ETHICON, ABC Corporations, 1-10, John Does, 1-10, and/or Jane Does, 1-10, (hereafter collectively referred to as "Defendants"), owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell products, including minimally invasive gynecologic products, including products used for uterine morcellation, specifically the MORCELEX product manufactured by defendant ETHICON in such a way as to avoid harm to persons upon whom they are used, such as Plaintiff herein, or to refrain from such activities

following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

18. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products, specifically minimally invasive gynecologic products, including products used for uterine morcellation, such as the MOCRELEX product manufactured by defendant ETHICON for patients such as plaintiff herein, so as to avoid harm.

19. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce, minimally invasive gynecologic products, including the MORCELEX morcellator, both generally, and in the following particular respects:

a. failing to conduct adequate and appropriate testing of minimally invasive gynecologic products, such as the MORCELEX morcellator, specifically including, but not limited to, products used for uterine morcellation;

b. putting products used for uterine morcellation such as the MORCELEX morcellator on the market without first conducting adequate testing to determine possible side effects;

c. putting products used for uterine morcellation such as the MORCELEX morcellator on the market without adequate testing of its dangers to humans;

d. failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, such as the MORCELEX morcellator, which testing evidenced such products potential harm to humans;

e. failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, such as the MORCELEX morcellator which indicated such products potential harm to human;

f. failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;

g. failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation, such as the MORCELEX morcellator.

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation in light of such products potential harm to humans;

i. failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge andexperience regarding the potential that products used for uterine morcellation, specifically the MORCELEX morcellator, are harmful to humans;

k. promoting, marketing, advertising and/or selling products used for uterine morcellation, such as the MORCELEX morcellator, for use on patients given their knowledge and experience of such products' potential harmful effects;

l. failing to withdraw products used for uterine morcellation from the market, restrict its use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

m. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products manufacturer engaged in the manufacture of said products, specifically including products used for uterine morcellation such as the MORCELEX morcellator, in among other things, failing to deploy an intraperitoneal bag with said morcellator to prevent the spread of malignancy.

n. placing and/or permitting the placement of the products used for uterine morcellation, specifically the MORCELEX morcellator into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation, including the MORCELEX morcellator to be harmful to humans;

p. failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients, including the MORCELEX morcellator;

q. disregarding the safety of users and consumers of products used for uterine morcellation, including plaintiff herein, under the circumstances by failing adequately to warn of said products' potential harm to humans;

r. disregarding the safety of users and consumers of the products used for uterine morcellation, including plaintiff herein, and/or her physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information

regarding the hazards of the products used for uterine morcellation and their potential harm to humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

u. failing to remove products used for uterine morcellation from the stream of commerce;

v. failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;

w. promoting the products used for uterine morcellation as safe and/or safer than other comparative methods of lesion removal;

x. promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand;

y. failing to conduct and/or respond to post-marketing surveillance of complications and injuries.

z. failing to use due care under the circumstances; and,

aa. such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter

20. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, Plaintiff suffered serious injuries, and/or financial losses and harm.

WHEREFORE, Plaintiff, BRENDA LEUZZI respectfully requests that this Honorable Court enter judgment in her favor and against ETHICON, and/or ABC Corporations, 1-10;

and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT II – STRICT PRODUCTS LIABILITY
ON BEHALF OF BRENDA LEUZZI

21. The paragraphs above are incorporated by reference hereto as if set forth at length.

22. As a result of the unreasonably dangerous and defective condition of the products used for uterine morcellation, specifically the MORCELEX morcellator, which defendants manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or placed into the stream of commerce, they are strictly liable to the Plaintiffs for their injuries which they directly and proximately caused, based on the following:

a. failing to properly and adequately design the products used for uterine morcellation, specifically the MORCECLEX morcellator, in order to prevent the potential spread of malignancy, by among other things, failing to deploy an intraperitoneal bag with said morcellartor.

23. In addition, the aforesaid incident and Plaintiff's injuries and losses were the direct and proximate result of Defendants' manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce the products used for uterine morcellation, specifically the MORCELEX morcellator without proper and adequate warnings regarding the potential for said products' harm to humans and as otherwise set forth supra, when said defendants knew or should have known of the need for such warnings and/or recommendations.

WHEREFORE, Plaintiff, BRENDA LEUZZI, respectfully requests that this Honorable Court enter judgment in her favor against ETHICON and/or ABC Corporations, 1-10; and/or

John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT III - BREACH OF EXPRESS WARRANTY
ON BEHALF OF BRENDA LEUZZI

24. The paragraphs above are incorporated by reference hereto as if set forth at length.

25. In the advertising and marketing of the products used for uterine morcellation, which was directed to both physicians and hospitals and consumers, Defendants warranted that said product or products, including the MORCELEX morcellator, were safe for the use, which had the natural tendency to induce physicians and hospitals to use the same for patients and for patients to want to be treated with the same.

26. The aforesaid warranties were breached by defendants in that the MORCELEX morcellator products used for uterine morcellation constituted a serious danger to the user.

27. As a direct and proximate result of defendants' breach of express warranty, Plaintiff suffered serious injuries, financial losses and harm.

WHEREFORE, Plaintiff, BRENDA LEUZZI respectfully requests that this Honorable Court enter judgment in her favor and against ETHICON, and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT IV – BREACH OF IMPLIED WARRANTY
ON BEHALF OF BRENDA LEUZZI

28. The paragraphs above are incorporated by reference hereto as if set forth at length.

29. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the MORCELEX morcellator used for uterine morcellation.

30. At all relevant times, defendants intended that the products used for uterine morcellation, including the MORCELEX morcellator, be used in the manner that the Plaintiff's surgeons in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

31. Defendants breached various implied warranties with respect to the products used for uterine morcellation, including:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products used for uterine morcellation, including the MORCELEX morcellator, were safe, and withheld and concealed information about the substantial risks of serious injury and/or death associated with using the products used for uterine morcellation;

b. Defendant represented that the products used for uterine morcellation, including, the MORCELEX morcellator, were as safe and/or safer than other alternative surgical approaches that did not include the use of the said products, and concealed information, which demonstrated that said products were not safer than alternatives available on the market; and,

c. Defendants represented that the products used for uterine morcellation, including the MORCELEX morcellator, were more efficacious than other alternative surgical approaches and techniques and concealed information, regarding the true efficacy of said products.

32. In reliance upon Defendants' implied warranty, Plaintiff's surgeons used said MORCELEX morcellator as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

33. Defendants breached their implied warranty to Plaintiff in that said MORCELEX morcellator used for uterine morcellation was not of merchantable quality, safe and fit for their intended use, or adequately tested.

34. As a direct and proximate consequence of Defendants' breach of implied warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiff sustained injuries and damages alleged herein including pain and suffering.

WHEREFORE, Plaintiff, BRENDA LEUZZI, respectfully requests that this Honorable Court enter judgment in his favor and against ETHICON and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees.

COUNT V
FRAUDULENT MISREPRESENTATION AND OMISSION

35. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

36. Defendant, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the MORCELEX morcellator owed a duty to provide accurate and complete information regarding said devices.

37. Prior to Plaintiff BRENDA LEUZZI undergoing her surgery defendants fraudulently misrepresented, that the use of their MORCELEX morcellator for uterine morcellation was safe and effective.

38. Defendant had a duty to provide Plaintiff BRENDA LEUZZI, physicians, and other consumers with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold.

39. Defendant made representations and failed to disclose material facts with the intent to induce consumers, including Plaintiff, BRENDA LEUZZI and the medical community to act in reliance by purchasing and using the MORCELEX uterine morcellator sold by defendant.

40. Plaintiff BRENDA LEUZZI and the medical community justifiably relied on Defendant's representations and omissions by purchasing and using the uterine morcellator during Plaintiff's surgery.

41. Defendant's representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of Plaintiff BRENDA LEUZZI's injuries.

WHEREFORE, Plaintiff, BRENDA LEUZZI, respectfully requests that this Honorable Court enter judgment in his favor and against ETHICON and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees

COUNT VI
LOSS OF SERVICES

42. That plaintiff, GEORGE LEUZZI., repeats, reiterates and realleges each and every allegation contained hereinabove in paragraphs with the same force and effect as if hereinafter fully set forth and further alleges as follows.

43. Plaintiff, GEORGE LEUZZI is the spouse of plaintiff BRENDA LEUZZI and as such is entitled to the services, society, companionship, consortium and support of the plaintiff, BRENDA LEUZZI.

44. That by reason of the foregoing acts and omissions by the defendants, plaintiff GEORGE LEUZZI., was deprived of the services, society, companionship, consortium and support of plaintiff, BRENDA LEUZZI.

WHEREFORE, Plaintiff, GEORGE LEUZZI, respectfully requests that this Honorable Court enter judgment in his favor and against ETHICON and/or ABC Corporations, 1-10; and/or John Does, 1-10, and/or Jane Does, 1-10, jointly and/or severally, in an amount in excess of $75,000.00 plus interest, costs, punitive damages, and attorney's fees

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of services, consortium, society and other non-economic damages in an amount to be determined at trial of this action;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Double or triple damages as allowed by law;

4. Restitution and disgorgement of profits;

5. Reasonable attorneys' fees;

6. Punitive damages;

7. The costs of these proceedings; and

8. Such other and further relief as this Court deems just and proper.

Dated: Melville, New York
May 1, 2014

Respectfully submitted,

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ATTORNEYS VERIFICATION

STATE OF NEW YORK)
: ss:
COUNTY OF NASSAU)

David B. Krangle, an attorney and counselor at law, duly admitted to practice in the Courts of the State of New York, affirms the following to be true under penalties of perjury:

I am a member/associate of the firm **ALONSO KRANGLE LLP** attorneys for the plaintiff(s) herein.

I have read the foregoing COMPLAINT and know the contents thereof. Upon information and belief, I believe the matters alleged therein to be true.

The source of your deponent's information and the grounds of my belief are communications, papers, reports and investigations contained in my file.

The reason this verification is made by deponent and not by plaintiff(s) is that plaintiff(s) reside in a county other than the one in which your deponent's office is maintained.

Dated: Melville, New York
May 1, 2014

David B. Krangle